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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,771

04/21/2004

Li Chen

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER

MABRY, JOHN

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

11/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,771	Applicant(s) CHEN ET AL.	
	Examiner John Mabry, PhD	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-20, 22-24, 30, 31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11, 13-20, 22-24, 30, 31 and 33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 13-20, 22-24 and 33 are drawn to compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=quinolinyl, and pharmaceutical acceptable salts thereof classified in class 546, subclass 152+. A further election of a single disclosed species is required.
- II. Claims 1-5, 8-9, 13-18, 22-24 and 33 are drawn to compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=isoquinolinyl, and pharmaceutical acceptable salts thereof classified in class 546, subclass 139+. A further election of a single disclosed species is required.
- III. Claims 1-5, 8-9, 13-18, 22, 30-31 and 33 are drawn to compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=pyridinyl, and pharmaceutical acceptable salts thereof

classified in class 546, subclass 250+. A further election of a single disclosed species is required.

- IV. Claims 1-5, 8-9, 13-18, 22 and 33 are drawn to compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=1,3-pyrimidinyl, and pharmaceutical acceptable salts thereof classified in class 544, subclass 242. A further election of a single disclosed species is required.
- V. Claims 1-5, 8-9, 13-18, 22 and 33 are drawn to compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=1,2,3-triazolyl, and pharmaceutical acceptable salts thereof classified in class 548, subclass 255. A further election of a single disclosed species is required.
- VI. Claims 1-5, 8-9, 13-18, 22 and 33 are drawn to compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=1,2-isoxazolyl, and pharmaceutical acceptable salts thereof classified in class 548, subclass 240. A further election of a single disclosed species is required.

- VII. Claims 1-5, 8-9, 13-18, 22 and 33 are drawn to compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=thiazolinyl, and pharmaceutical acceptable salts thereof classified in class 548, subclass 146. A further election of a single disclosed species is required.
- VIII. Claims 1-5, 8-9, 13-18, 22 and 33 are drawn to compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=pyrazolo[1,5-a]pyrimidinyl, and pharmaceutical acceptable salts thereof classified in class 544, subclass 245. A further election of a single disclosed species is required.
- IX. Claims 1-5, 8-9, 13-18, 22 and 33 are drawn to compounds of Formula I that are not encompassed by Groups I-VIII. Classification is dependent upon species elected. A further election of a single disclosed species is required. This group may be subject to further restriction.

The inventions are distinct, each from the other because of the following reasons:

Groups I – IX are independent and distinct from each other as they are drawn to compounds of formula I with different divergent moieties in the X, X', Z and Y positions. Group I require compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is

of formula X-7 wherein Het=quinolinyl. Group II require compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=isoquinolinyl. Group III require compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=pyridinyl. Group IV require compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=1,3-pyrimidinyl. Group V require compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=1,2,3-triazolyl. Group VI require compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=1,2-isoxazolyl. Group VII require compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=thiazolinyl. Group VIII require compounds of Formula I, wherein Y=5-, 6-membered carbocyclic, X is of formula X-7 wherein Het=pyrazolo[1,5-a]pyrimidinyl. Group IX require compounds of Formula I that are not encompassed by Groups I-VIII.

The compounds of group IX do not fall within groups I – VIII. Each of groups I - IX are directed to compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of actions, different effects, and reactive conditions. Each of groups I – IX have different classifications and subclasses. It is noted that a reference disclosing a compound of one group would not necessarily disclose a compound of the other groups. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e. they are patentable over each other. Chemical structures

that are similar are presumed to function similarly, while chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Thus, by virtue of the different structures presented in groups I - IX, these inventions are distinct.

Because these inventions are distinct for the reasons given above and the search required for group I is not required for groups II - IX, restriction for examination purposes as indicated is proper. Groups I - IX are not identically classified under U.S. Patent Classification guidelines, thus, to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. Thus, groups I - IX have been appropriately restricted on the basis of being both independent or distinct and presenting an undue search burden on the Examiner if they were to be searched together.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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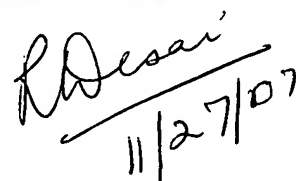
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JM

RITA DESAI
PRIMARY EXAMINER


11/27/07